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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,859	07/30/2003	Gary F. Gerard	IVGN 338	6152

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EXAMINER	
BURKHART, MICHAEL D	
ART UNIT	PAPER NUMBER
1633	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/629,859	GERARD, GARY F.	
	Examiner	Art Unit	
	Michael D. Burkhart	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9,11-17,19-21 and 26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9,11-17,19-21 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt and entry of the amendment dated 4/18/2007 is acknowledged. After entry of the amendment, claims 9, 11-17, 19-21 and 26 are pending and under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action. Rejections and/or objections not reiterated from the previous Office Action are hereby withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **This is a new rejection necessitated by amendment of the claims.**

Claim 11 recites the limitation "the corresponding wild-type or RNase H^+ polypeptide" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9, 12-14, 17, 19-21 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Rothenberg et al (J. Virol., 1974) as evidenced by Murray et al (Medical Microbiology, 1998). **This is a new rejection necessitated by amendment of the claims.**

Rothenberg et al teach disrupted virions of Moloney murine leukemia virus (MMLV) that comprise the MMLV reverse transcriptase (RT) (abstract, page 168, second column, second full ¶). The disrupted virions were used in reverse transcriptase reactions to synthesize DNA from the 35S RNA subunit of the viral genome (abstract, page 168). Reaction conditions included using dNTPs at 15.2 mM and Mg^{+2} at 12mM and 9mM (pages 169-170 and Fig. 1). The viral genome is considered messenger RNA, absent a precise definition in the specification, and

because retroviruses have a positive-strand RNA genome, i.e. RNA that can code for proteins and thus resembles mRNA (see page 509 of Murray et al). Regarding claim 19, reverse transcriptases are RNA-dependent DNA polymerases, and thus are considered to meet the limitation that the reaction mix include a DNA polymerase. Kits are merely a localized collection of components, and as such it is considered that the presence of all the components of the instant claims in the same tube (i.e. as in the RT assay experiments) is a "kit."

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11 and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rothenberg et al (J. Virol., 1974) as applied to claims 9, 12-14, 17, 19-21 and 26 above, and further in view of Schwabe et al (FOCUS, 1998, of record). **This is a new rejection necessitated by amendment of the claims**

The teachings of Rothenberg et al are described above and applied as before. Furthermore, Rothenberg et al teach the desirability of limiting the free Mg+2 concentration during reverse transcription reactions by chelation with excess dNTPs in order to stabilize the RNA template (abstract; page 168, the beginning of the second column; and the Discussion, beginning on page 175). Rothenberg et al do not teach the use of a polypeptide with reduced RNaseH activity, or the temperature range recited in claim 15.

Schwabe et al disclose a method for first strand synthesis from an mRNA template and subsequent PCR amplification of the first strand, which necessarily comprises second strand synthesis. RNA isolated from HeLa cells or rat brain were used with oligo dT as the primer for first strand synthesis (see page 30, first column last paragraph and page 31 first column, top). PCR was performed with the *Taq* DNA polymerase to amplify the cDNA produced (page 31,

first column). Schwabe et al disclose an avian RT with reduced RNase H activity, important for synthesis of long cDNAs (page 30, first column, first paragraph). The first strand synthesis is carried out at temperatures ranging from 42-58°C (see Figure 2).

The claimed compositions and methods of reverse transcription or nucleic acid amplification are essentially disclosed by Rothenberg et al with the exception of the reduced RNase H activity and temperature limitations. The ordinary skilled artisan, seeking a method to perform RT or RT-PCR assays, would have been motivated to use the RT with reduced RNase H activity and temperature conditions of Schwabe et al with the methods of using excess dNTPs relative to Mg^{+2}-, as taught by Rothenberg et al, because both Schwabe et al and Rothenberg et al teach these reagents and methods to be effective means of solving the problem of RNA degradation during RT reactions. It would have been obvious for the skilled artisan to do this because of the known benefit of generating increased levels of DNA synthesis, and longer DNA transcripts, as taught by Rothenberg et al and Schwabe et al. Given the teachings of the cited references and the level of skill of the ordinary skilled artisan at the time of applicants' invention, the ordinary skilled artisan would have had a reasonable expectation of success in practicing the claimed invention because optimization of factors affecting the reverse transcriptase reaction has been routine in the art at the time the instant invention was filed. Thus the invention as claimed is *prima facie* obvious in view of cited prior art of record.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael D. Burkhart whose telephone number is (571) 272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael D. Burkhart
Examiner
Art Unit 1633

SUMESH KAUSHAL, PH.D.
PRIMARY EXAMINER